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Azitra, Inc. (AZTR: NYSE)

AZTR: First ATR-12 Patient Screened

Azitra's valuation relies on a DCF model and a 15% discount rate applied to our cash flow estimates for commercialization of ATR-12 in Netherton syndrome. We apply a success probability of 20% to the program. The model includes contributions from the United States and the developed world.

Current Price (8/22/2024)	$0.75
Valuation	**$4.00**

OUTLOOK

Azitra is developing genetically engineered bacteria for therapeutic use in dermatology. The company possesses a microbial library of 1,500 unique bacterial strains that are candidates for a variety of indications. Azitra's lead candidate is ATR-12 for the rare disease Netherton Syndrome (NS). A second candidate is ATR-04 targeting EGFRi-associated rash and a third, ATR-01, ichthyosis vulgaris. Each one is topically formulated.

Preclinical work has shown effective and safe use of ATR-12 as a potentially disease-modifying therapy able to colonize the skin and replace the missing LEKTI protein. An IND has been cleared and Azitra has started a Ph1 for NS. An IND is expected for ATR-04 by year end 2024.

ATR-12 provides the missing active protein segment for NS and if successful will be a disease modifying therapy. The therapy is not a cure and patients will require ongoing treatment.

We expect clinical trials for NS will follow an expedited pathway as NS is a rare disease that affects children. Our forecasts call for Ph2 and pivotal trials producing a BLA submission in 2028 and approval the following year. ATR-12 may also qualify for a rare pediatric disease priority review voucher which may hold substantial value if sold.

SUMMARY DATA

52-Week High	**6.70**
52-Week Low	**0.58**
One-Year Return (%)	**-98.6**
Beta	**1.2**
Average Daily Volume (sh)	**2,861,950**
Shares Outstanding (mil)	**7.6**
Market Capitalization ($mil)	**5.7**
Short Interest Ratio (days)	**0.1**
Institutional Ownership (%)	**8.6**
Insider Ownership (%)	**10.6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**N/A**
P/E using 2025 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2024	$0.5 A	$0.3 A	$0.0 E	$0.0 E	$0.0 E
2025					$0.0 E
2026					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2023					-$54.76 A
2024	-$4.36 A	-$2.74 A	-$0.48 E	-$0.50 E	-$3.06 E
2025					-$0.95 E
2026					-$0.66 E

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WHAT'S NEW

Azitra, Inc. (NYSE: AZTR) reported second quarter results following a $10 million raise which enabled the company to begin enrolling its ATR-12 Phase Ib trial for Netherton Syndrome. Just days after the 2Q:24 report, the company announced that the first patient for the ATR-12 trial had been screened and scheduled to initiate treatment before the end of August. A few days later, the company announced that its ATR-04 investigational new drug (IND) application for EGFRi-related skin rash was cleared by the FDA. A Phase I/II study is planned for year-end 2024.

Year to date, Azitra has been granted several patents for its ATR-12 and ATR-04 candidates, presented at numerous conferences and strengthened its balance sheet in order to advance its engineered bacterial candidates in dermatology. We recently initiated on Azitra providing a review of Netherton Syndrome, the competitive environment and factors impacting and contributing to our valuation of the enterprise. Below we provide a summary of second quarter results.

Operational and Financial Results

Azitra reported 2Q:24 results in a press release and Form 10-Q filing with the SEC on August 12th. For the second quarter of 2024 ending June 30, 2024 and versus the prior year's comparable period, revenues of $7,500 were reported compared with $172,000 in the prior year. Net loss for the quarter totaled ($2.6) million or ($2.74) per share. Operational expenses rose 61% as increases in both research and development (R&D) expenses and general and administrative (G&A) expenses were recognized. Below, we summarize financial results for the three-month period ended June 30, 2024, compared to the same prior year period:

- Revenues were $7,500, down from $113,000 with amounts in both periods related to the Bayer joint development agreement (JDA);
- Research and development expenses totaled $1.1 million, up from $0.8 million with the increase attributable to moving ATR-12 into the clinic and the use of clinical consultants in the most recent period;
- General & Administrative expenses were $1.5 million, up from $0.8 million on account of the addition of new personnel, costs related to becoming a public company, CFO consulting costs, premiums for directors' and officers' insurance, investor and public relations costs, conference costs and an increase in other overhead expenses partially offset by a decrease in accounting and auditing expenses;
- Net interest income was $14,000 compared to net interest expense of ($76,000) due to lower debt and higher cash balances;
- Other income was $14,000 vs. ($2.9) million due to the absence of a negative change in fair value of a convertible note in the prior year;
- Net loss was ($2.6) million vs. ($4.4) million;

As of June 30, 2024, cash totaled $0.8 million. This amount compares to the $1.8 million balance in cash held at the end of 2023. No debt was held on the balance sheet. For the first six months of the year, cash burn was ($5.3) million versus ($3.2) million for the same period in 2023. Net proceeds from the $5 million raise in February were $4.3 million. In July, Azitra closed another capital raise that produced $10 million in gross proceeds.

ATR-12 Clinical Trials

Azitra received investigational new drug (IND) clearance for its treatment of Netherton Syndrome, ATR-12 in January 2023. The company has launched a Phase Ib clinical trial under the identifier NCT06137157 and expects to enroll 12 patients. Primary endpoints will examine safety and tolerability while secondary and exploratory endpoints will assess efficacy signals and biomarkers. ATR-12 will be topically administered using twice-daily treatment. A clinical site at Yale University and Stanford University have been established and other sites are being sought.

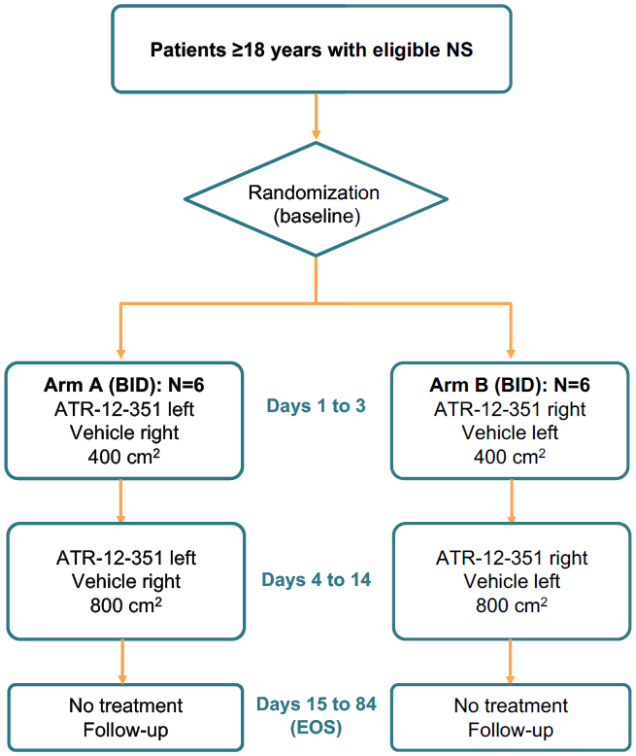
The study will apply ATR-12 to lesions on one side of a subject's body and apply the vehicle to the other. Application of ATR-12 and the vehicle will be performed twice daily for two weeks. Patients will be randomized to receive ATR-12 on either the right or left side.

The primary endpoint is adverse events at 84 days as well as quantifying or qualifying incidence, severity, seriousness and relatedness. Secondary endpoints include investigators' and patients' global assessment of severity, concentration of recombinant human lymphoepithelial Kazal-type related inhibitor (rhLEKTI) in the plasma and on the

skin following topical application. Biomarkers will be evaluated including KLK5, KLK7, IL-36, TARC/CCL17, trypsin-like activity and chymotrypsin-like activity.

The ongoing Phase I study for ATR-12 may evolve into a proof-of-concept trial that could enroll up to 20 patients including those in the Phase I portion. If supportive, the Phase II could lead to a larger pivotal trial acceptable to the FDA for BLA submission and approval.

Exhibit I – ATR-12 Trial Design



Source: Azitra SID Poster, May 2024

First Patient Screened

Azitra screened its first patient in the ATR-12 trial in August as reported in a press release. The patient is scheduled to initiate treatment by the end of the month. Interim safety data are expected to be available in early 2025 with full results available in 2H:25.

ATR-04

Epidermal growth factor receptor inhibitors (EGFRi) are targeted cancer therapies that have been effective in breast, colon, lung and pancreatic cancer. EGFR is a protein found on the surface of cells, and it plays a role in cell growth and division. In some cancers, such as certain types of lung cancer and colorectal cancer, the EGFR gene is mutated or overexpressed, leading to uncontrolled cell growth. EGFR inhibitors work by blocking the activity of this protein, thereby slowing down or stopping cancer cell growth.

In the skin, EGFR regulates multiple keratinocyte functions including proliferation, adhesion and migration, survival, and differentiation. Consequently, inhibition of EGFR in the skin results in adverse skin reactions, which make it difficult for patients to continue therapy. Two of the leading EGFR inhibitors, erlotinib and gefitinib, carry FDA labels that warn of rash and skin reactions in over 20% of patients. In many cases it is severe enough for the individual to stop EGFRi therapy. The skin reaction, which is referred to as an acneiform or papulopustular rash, can vary in intensity. Mild rash is treated with topical medications and oral antibiotics; however, in severe cases a doctor may stop treatment.

The side effect is an unmet need that may be addressed using ATR-04, which is a genetically modified strain of SE. The strain demonstrated properties of inhibiting IL-36γ, *S. aureus* and related biofilms. ATR-04 has been modified to be auxotrophic for D-alanine. The product is formulated as a topical application and may also help reduce the use of antibiotics, allow for better compliance with EGFRi regimens and improve patient quality of life.

ATR-04 is a drug product derived from an *S. epidermidis* strain and is administered topically. It was sourced from a healthy volunteer and engineered to be auxotrophic to control growth. The product inhibits IL-36γ and *S. aureus* both of which can cause and exacerbate inflammatory skin conditions. ATR-04 also increases human beta defensin 2 which provides antimicrobial benefits, maintains skin barrier functions and contributes to the wound healing process by preventing infections and regulating the inflammatory response.

Preclinical work for ATR-04 was completed and assembled with other required data into an investigational new drug (IND) application, which was submitted earlier this summer to the FDA. In an August 22nd press release, Azitra announced that that the IND had been cleared which allows the company to begin its Phase I/II study of ATR-04 for moderate to severe EGFRi associated dermal toxicity. The multicenter, randomized, controlled trial is expected to begin by the end of 2024.

Capital Raise

On July 25th, Azitra announced that it had closed a $10 million public offering which allowed the company to begin screening and enrolling patients in its Phase Ib Netherton Syndrome trial. The company issued 6.665 million units that consist of one underlying share and two warrants at an offering price of $1.50. The warrants have an exercise price of $1.50 and a duration of five years.

Conference Presentations

Azitra has been busy attending conferences and presenting its data to stakeholders. The company sent representatives to the American Society of Gene and Cell Therapy (ASGCT), Society of Investigative Dermatology (SID) and American Society of Clinical Oncology (ASCO) meetings. The topics ranged from a discussion of preclinical data for ATR-04 and its use in EGFR inhibitor-induced dermal toxicity to ATR-12 and its use of *Staphylococcus epidermidis* as a protein delivery system for treating skin diseases. Chief Operating Officer Travis Whitfill traveled to San Diego in June to attend the 2024 BIO International Convention providing a corporate update to participants including the status of the ATR-12 program and offering 1:1 meetings.

Patents

Azitra gained several new patent grants earlier this year strengthening its intellectual property portfolio in the areas of using its proprietary bacterial strains in atopic dermatitis and other skin diseases. The patents were granted in the U.S., China and Canada. Patents were issued with the following titles:

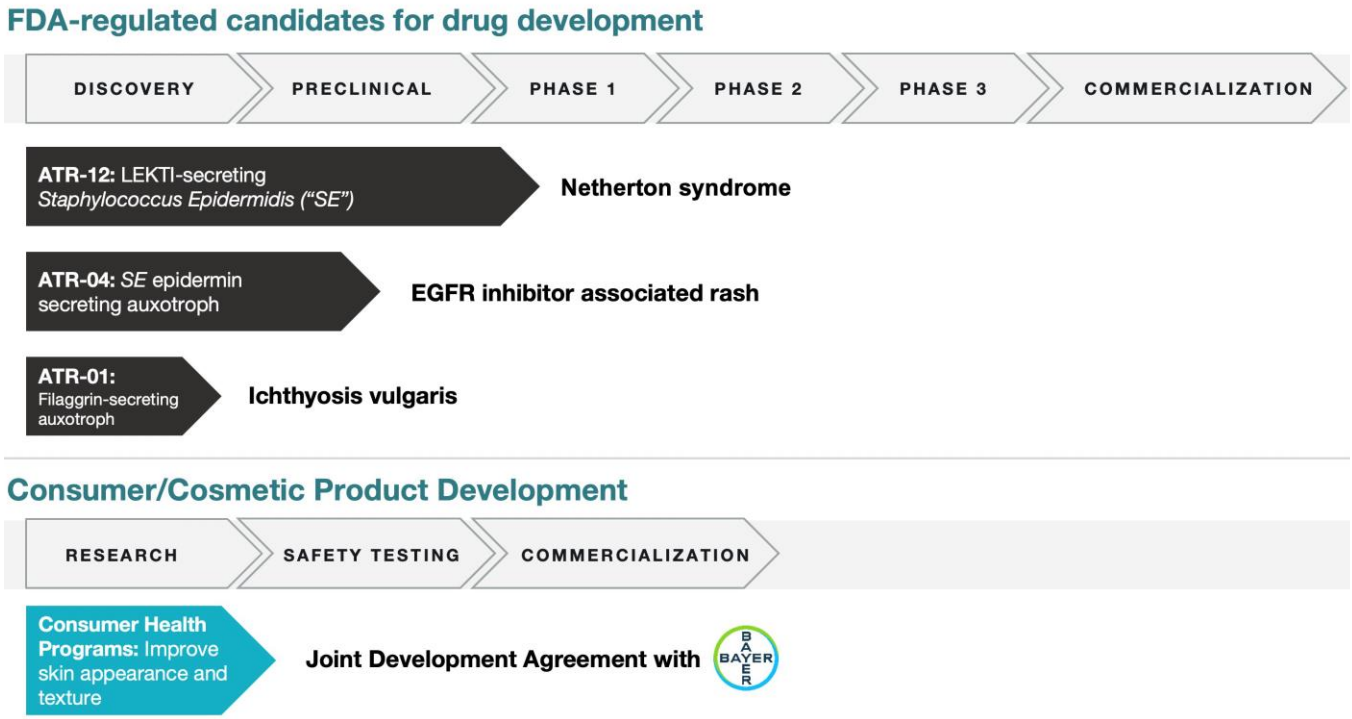
- Methods and Compositions for Treating Inflammatory Skin Disease with Recombinant Microorganisms
  - U.S. Patent Application No. 16/121,903
  - Covers the composition of filaggrin-secreting strains of Staphylococcus epidermidis
- Methods and Compositions for Treating Atopic Dermatitis with Recombinant Microorganisms
  - Canadian Patent Application No. 2979079
  - Covers the use of filaggrin-secreting strains of Staphylococcus epidermidis for atopic dermatitis and other skin diseases
- Methods and Compositions for Treating Inflammatory Skin Disease with Recombinant Microorganisms
  - Chinese Patent Application No. 201880071303.9
  - Covers the composition of filaggrin-secreting strains of Staphylococcus epidermidis

Following these issuances, Azitra will hold four granted U.S. patents, 14 granted international patents, nine pending U.S. patent applications and 44 pending international patent applications.

Milestones

- Filaggrin patent granted (#11,850,267) – January 2024
- ATR-12 presentation at ASGCT meeting – May 2024
- Presentation at the BIO International Convention – June 2024
- 1:30 reverse stock split – July 2024
- Closing of $10 million public offering – July 2024
- Dosing of first patient for ATR-12 – August 2024
- IND clearance by FDA for ATR-04 – August 2024
- Topline results from Phase Ib ATR-12 trial – 4Q:24

Exhibit II – Azitra Pipeline



Source: Azitra 2Q:24 10-Q

Initiation

We initiated coverage of Azitra with a target price of $4.00 per share in July based on our forecasts for the successful development and commercialization of ATR-12 for Netherton syndrome (NS). Azitra is a precision dermatology company developing a bacterial cell library guided by artificial intelligence and machine learning discovery. Its candidates are derived from a microbial genetic engineering platform that can produce molecules and peptides for precision dermatology. For its lead indication in Netherton Syndrome, Azitra has developed ATR-12, a LEKTI-secreting Staphylococcus epidermidis (SE) strain of bacteria that can inhibit the overactive proteases through LEKTI fragment secretion.

Key reasons to own Azitra shares:

- **Established company in the development of live biotherapeutic candidates**
- **Pipeline of bacterial strains able to deliver missing proteins to the skin**
  - **Gene engineering platform can enhance performance**
  - **Artificial intelligence & machine learning tools to identify candidates**
- **Pipeline with multiple dermatology assets**
  - **ATR-12: Phase I product for Netherton syndrome (NS)**
    - **May qualify for pediatric priority review voucher**
  - **ATR-04: preclinical product for EGFR inhibitor associated rash**
    - **Opportunity for partnership with EGFRi sponsors**
  - **ATR-01: preclinical product for ichthyosis vulgaris**
- **Joint Development Agreement with Bayer**
  - **Potential for milestones & royalties**
- **Global rights to intellectual property**

In the initiation report, we provide background on precision dermatology, the microbiome, live biotherapeutic products and commensal bacteria. Our focus narrows with a description and discussion of the technology and utility behind Azitra's bacterial library. Next, is a review of the company's lead candidate, ATR-12 which is a genetically modified strain of *Staphylococcus epidermidis* intended to treat NS. We continue with a description of the other pipeline candidates, ATR-04 and ATR-01 as well as a review of the Bayer collaboration. We conclude our report with the assumptions behind our valuation.

Summary

Azitra reported second quarter results in mid-August followed shortly after by an announcement that the first patient in the ATR-12 trial had been screened. A few days later, FDA clearance was granted for ATR-04's IND. Management has guided towards the first ATR-12 patient being enrolled before the end of August and for the ATR-04 study to begin around year end. This activity was enabled through the closing of a $10 million equity offering in late July which should provide sufficient funding to complete the ATR-12 Phase I trial and start the ATR-04 trial. We remind investors that Azitra has submitted preclinical data to Bayer for consumer health candidates. The data is being considered and if the slow-moving large pharmaceutical company decides to advance the program, it could provide an attractive upfront payment. We maintain our recently generated price target of $4.00 per share.

PROJECTED FINANCIALS

Azitra, Inc. - Income Statement

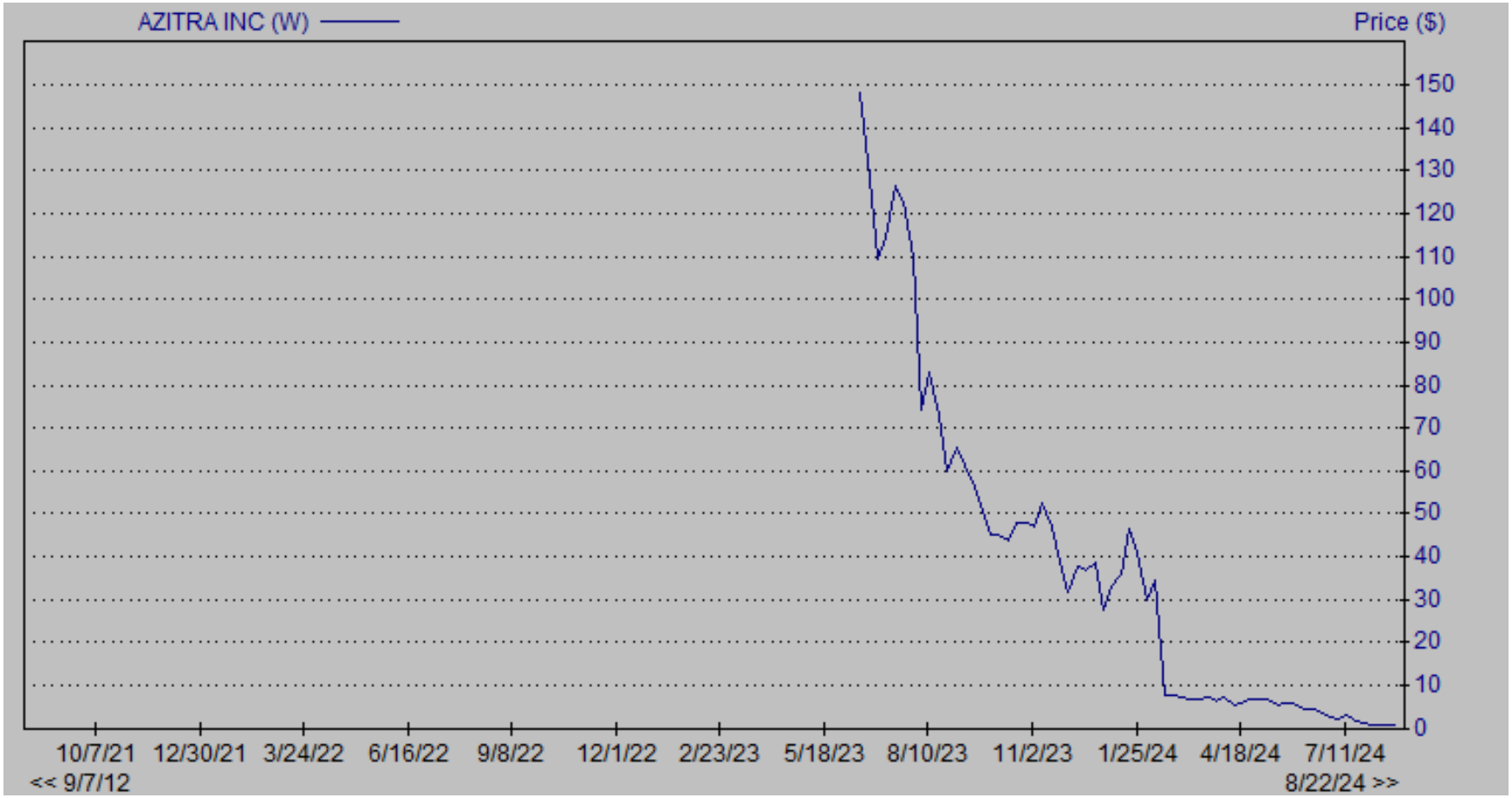
Azitra, Inc.	2023 A	Q1 A	Q2 A	Q3 E	Q4 E	2024 E	2025 E	2026 E
Revenues	**$686**	**$0**	**$8**	**$0**	**$0**	**$8**	**$0**	**$0**
General & Administrative	$4,493	$1,489	$1,549	$1,120	$1,132	$5,290	$5,200	$5,500
Research & Development	$3,809	$1,473	$1,119	$2,599	$2,820	$8,011	$9,000	$9,100
Operating Income	($7,616)	($2,961)	($2,660)	($3,719)	($3,952)	($13,293)	($14,200)	($14,600)
Operating Margin								
Interest Expense, net	($166)	$7	($2)	$0	$0	$5	$0	$0
Other Income (Loss)	($3,484)	$22	$30	$0	$0	$52	$0	$0
Loss Before Income Taxes	($11,266)	($2,933)	($2,632)	($3,719)	($3,952)	($13,236)	($14,200)	($14,600)
Income Tax	($17)	$0	$0	$0	$0	$0	$0	$0
Net Loss	**($11,284)**	**($2,933)**	**($2,632)**	**($3,719)**	**($3,952)**	**($13,236)**	**($14,200)**	**($14,600)**
Preferred Stock Dividends	($1,355)	$0	$0	$0	$0	$0	$0	$0
Net Loss Per Share	**($54.76)**	**($4.36)**	**($2.74)**	**($0.48)**	**($0.50)**	**($3.06)**	**($0.95)**	**($0.66)**
Weighted Average Shares	231	673	960	7,700	7,950	4,321	15,000	22,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Azitra, Inc. – Share Price Chart



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